Docket No.

203512US77

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

William M. CANFIELD

SERIAL NO:

10/023.889

December 21, 2001

GAU:

1645

EXAMINER:

FOR:

FILED:

METHOD OF PRODUCING HIGH MANNOSE GLYCOPROTEINS IN COMPLEX CARBOHYDRATE

DEFICIENT CELLS

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

RECEIVED

SIR:

Applicant(s) wish to disclose the following information.

AUG 0 1 2003

TECH CENTER 1600/2900

REFERENCES

- The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- △ A check is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- A check is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- □ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

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Tel. (703) 413-3000 Fax. (703) 413-2220 (OSMMN 05/03)

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SHEET 1 OF 3

SERIAL NORECEIVE ATTY DOCKET NO. U.S. DEPARTMENT OF COMMERCE Form PTO 1449 (Modified) PATENT AND TRADEMARK OFFICE 203512US77 APPLICANT AUG 0 1 2003 LIST OF REFERENCES CITED BY APPLICANT William M. CANFIELD FILING DATE December 21, 2001 **U.S. PATENT DOCUMENTS** FILING DATE SUB **EXAMINER** DOCUMENT DATE NAME CLASS CLASS IF APPROPRIATE NUMBER INITIAL AΑ AB AC ΑD ΑE AF AG ΑH ΑI ΑJ ΑK AL AM ΑN **FOREIGN PATENT DOCUMENTS** DOCUMENT TRANSLATION DATE COUNTRY NUMBER YES NO 99/31117 06/24/99 **WIPO** AO ΑP AQ AR OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.) Ke-Wei ZHAO, et al., "Purification and characterization of human lymphoblast N-acetylglucosamine-1-phosphotransferase", AS Glycobiology, Vol. 2, no. 2, pp. 119-125, 1992 Takahiro NAGASE, et al., "Prediction of the Coding Sequences of Unidentified Human Genes. XV. The Complete Sequences of 100 New(cDNA Clones from Brain Which Code for Large Proteins in vitro", DNA Research, Vol. 6, pp. 337-ΑT 345, 1999 XP-002226188, "KIAA1208 protein (Fragment)", From Takahiro NAGASE, et al., "Prediction of the Coding Sequences of Unidentified Human Genes. XV. The Complete Sequences of 100 New(cDNA Clones from Brain Which Code for Large Proteins in vitro", DNA Research, Vol. 6, pp. 337-345, 1999 XP-002226187, "Basic domain/leucine zipper transcription factor (Fragment), From CORDES, et al., "The mouse segmentation gene kr encodes a novel Additional References sheet(s) attached ΑV basic domain-leucine zipper transcription factor" (1994), Cell, Vol. 7, No. 9, pp.1025-1034 Examiner Date Considered *Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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SHEET 2 OF 3

SERIAL NO. ATTY DOCKET NO. U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE Form PTO 1449 (Modified) 10/023,889 **RECEIVE**D 203512US77 **APPLICANT** LIST OF REFERENCES CITED BY APPLICANT William M. CANFIELD AUG 0 1 2003 **GROUP** FILING DATE 1645 December 21, 2001 TECH CENTER 1600 2900 **U.S. PATENT DOCUMENTS** SUB FILING DATE **EXAMINER** DOCUMENT NAME CLASS DATE **CLASS** IF APPROPRIATE INITIAL NUMBER BA BB BC BD RE BF BG BH ы BJ ВK BL вм BN FOREIGN PATENT DOCUMENTS DOCUMENT TRANSLATION DATE COUNTRY NUMBER YES NO во BP BO BR BS BT BU ΒV OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.) Karen Gheesling MULLIS, et al., "Purification and Kinetic Parameters of Bovine Liver N-Acetylglucosamine-1-phosphodiester BW alpha-N-Acetylglucosaminidase", The Journal of Biological Chemistry, Vol. 269, No. 3, Issue of January 21, pp. 1718-1726, Jin Kyu LEE, et al., "Purification and Characterization of Human Serum N-Acetylglucosamine-1-phosphodiester alpha-N-Acetylglucosaminidase", Archives of Biochemistry and Biophysics, Vol. 319, No. 2. June 1, pp. 413-425, 1995 RX Theodore PAGE, et al., "Purification and characterization of human lymphoblast N-acetylglucosamine-1-phosphodiester BY alpha-N-acetylglucosaminidase", Glycobiology, Vol. 6, no. 6, pp. 619-626, 1996 Thomas J. BARANSKI, et al., "Lysosomal Enzyme Phosphorylation", The Journal of Biological Chemistry, Vol. 267, No. 32, Issue of November 15, pp. ΒZ Additional References sheet(s) attached 23342-23348, 1992 Examiner Date Considered *Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

JUL 3 1 2803 & SHEET 3 OF 3

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Europäisches Patentamt

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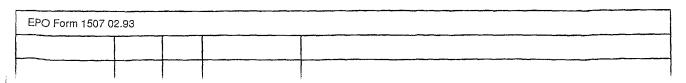
nmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire Canfield, William M.

COMMUNICATION

	Commonication
The Europe	ean Patent Office herewith transmits
	the European search report
	the declaration under Rule 45 EPC
	the partial European search report under Rule 45 EPC
X I	the supplementary European search report concerning the international application under Article 157(2) EPC relating to the above-mentioned European patent application. Copies of the documents cited in the search report are enclosed.
The followi	ng specifications given by the applicant have been approved by the Search Division :
	Abstract Title Figure
	The abstract was modified by the Search Division and the definitive text is attached to this communication.
	The following figure will be published with the abstract, since the Search Division considers that it better characterises the invention than the one indicated by the applicant.
	Figure:
×	Additional copy(copies) of the documents cited in the European search report.

REFUND OF THE SEARCH FEE

If applicable under Article 10 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.







CLAIMS INCURRING FEES
The present European patent application comprised at the time of filing more than ten claims.
Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.
LACK OF UNITY OF INVENTION
The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:
see sheet B
All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
1-67, 74-105
None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

INCOMPLETE SEARCH SHEET C

Application Number

EP 00 96 1335

Although claims 74-81 are directed to a method of treatment of the human/animal body (Article 52(4) EPC), the search has been carried out and based on the alleged effects of the compound/composition.

Claim(s) searched incompletely: 43, 49, 52, 57, 67, 69, 76, 79, 80

Reason for the limitation of the search:

Present claims 43, 52, 67, 69, 76, 79 and 80 and especially Claims 49 and 57 relate to an extremely large number of possible compounds or methods. Support within the meaning of Article 84 EPC and/or disclosure within the meaning of Article 83 EPC is to be found, however, for only a very small proportion of the compounds or methods claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Unless the alternatives in said claims 43, 52, 67, 69, 76, 79 and 80 relate to a claim which itself is novel and inventive, they will give rise to further non-unity objections.

The same applies for claims 49 and 57 provided an attempt will be made to specify the compounds claimed.

In this context it should be emphasised that the drafting of the claims lies exclusively in the reponsability of the Applicant and that e.g. non-unity objections which arise due to the drafting of certain subject-matter in an independent form, cannot be cured by making refernce to the fact that said indpendently claimed subject-matter forms part of a common (but unfortunately known) concept, e.g. two independently claimed steps of a known process.

LACK OF UNITY OF INVENTION SHEET B

Application Number

EP 00 96 1335

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-18, 82, 84, 86, 88-105

GlcNAc-phosphotransferase and subunits thereof, an antibody binding it, nucleotide sequences encoding it or encoding the subunits, methods for producing the enzyme, vectors and host cell comprising the nucleotide sequences coding for the enzyme or the subunits

2. Claims: 19-34, 83, 85, 87

Phosphodiester alpha-GlcNAcase, an antibody binding it, nucleotide sequence encoding it, vectors and host cells comprising the nucleotide sequence and methods for producing the enzyme

3. Claims: 35-48

Method of modifying lysosomal hydrolases comprising contacting said lysosomal hydrolases with an isolated GlcNAc-phosphotransferase

4. Claims: 49-67

Phosphorylated lysosomal hydrolase comprising a mannose 6-phosphate amnd methods for preparing phosphorylated lysosomal hydrolase

5. Claims: 68-73

High mannose lysosomal hydrolase and methods for producing it

6. Claims: 74-81

Methods of treating a patient suffering from a lysosomal storage disease

SUPPLEMENTARY



PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent ConventionEP 00 96 1335 shall be considered, for the purposes of subsequent proceedings, as the European search report

	DOCUMENTS CONSID	ERED TO BE RELEVANT]
Category	<u></u>	ndication, where appropriate,	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.CI.7)
X Y	CHARACTERIZATION OF		35-48	C12N9/12 C12N9/14 C12N1/20 C12N15/00 C07H21/04 A61K38/44 A61K38/51 C07K14/00
The si	upplementary search report has b	een based on the last set of claims vali	d	TECHNICAL FIELDS SEARCHED (Int.CI.7)
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not comp be carried Claims se Claims se Claims no Reason for	ch Division considers that the present ly with the EPC to such an extent that dout, or can only be carried out partial earched completely: earched incompletely: of searched: or the limitation of the search: sheet C	application, or some or all of its claims, does a meaningful search into the state of the art lly, for the following claims:	/do cannot	
	Place of search	Date of completion of the search 26 March 2003	Cna	Examiner
X : part Y : part doc A : tect O : nor	MUNICH CATEGORY OF CITED DOCUMENTS dicularly relevant if taken alone ticularly relevant if combined with another than the same category anological background another than the same category anological background another than the same category and the same category	le underlying the curnent, but publicte in the application of other reasons	lished on, or	

SUPPLEMENTARY



European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

EP 00 96 1335

	DOCUMENTS CONSIDERED TO BE RELEVANT		CLASSIFICATION OF THE APPLICATION (Int.CI.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
P,X	NAGASE T ET AL: "PREDICTION OF THE CODING SEQUENCES OF UNIDENTIFIED HUMAN GENES. XV.THE COMPLETE SEQUENCE OF 100 NEW CDNA CLONES FROM BRAIN WHICH CODE FOR LARGE PROTEINS IN VIVO" DNA RESEARCH, UNIVERSAL ACADEMY PRESS, JP, vol. 6, no. 5, October 1999 (1999-10), pages 337-345, XP000865804 ISSN: 1340-2838	8-10, 88-99	
P,X	see the whole document -& DATABASE SWALLPROT 'Online! 1 May 2000 (2000-05-01) retrieved from EBI Database accession no. Q9ULL2 XP002226188 * abstract * 99.8% ientity with SEQ ID NO: 1 from aa 308-930 and 100% identity with SEQ ID NO: 2	8-10, 88-99	TECHNICAL FIELDS SEARCHED (Int.CI.7)
X	DATABASE SWALLPROT 'Online! 1 November 1996 (1996-11-01) retrieved from EBI Database accession no. Q61340 XP002226187 57.9% identity with SEQ ID NO: 1 in 285 aa overlap (aa 645-930 of SEQ ID NO: 1)	8-10,91	
х	WO 99 31117 A (FLORENCE KIMBERLY; HUMAN GENOME SCIENCES INC (US); FENG PING (US);) 24 June 1999 (1999-06-24) Human secreted protein encoded by gene 6 has 100% identity with SEQ ID NO: 3 see SEQ ID NO: 130	8-10, 102-105	
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SUPPLEMENTARY



PARTIAL EUROPEAN SEARCH REPORT

Application Number

EP 00 96 1335

1	DOCUMENTS CONSIDERED TO BE RELEVANT	CLASSIFICATION OF THE APPLICATION (Int.CI.7)	
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
	MULLIS KAREN GHEESLING ET AL: "Purification and kinetic parameters of bovine liver N-acetylglucosamine-1-phosphodiester alpha-N-acetylglucosaminidase." JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 269, no. 3, 1994, pages 1718-1726, XP002235767 ISSN: 0021-9258	19,20	
Y	see the whole document	21-34, 50-56	
X	LEE JIN KYU ET AL: "Purification and Characterization of Human Serum N-Acetylglucosamine-1-phosphodiester alpha-N-Acetylglucosaminidase." ARCHIVES OF BIOCHEMISTRY AND BIOPHYSICS, vol. 319, no. 2, 1995, pages 413-425, XP002235768 ISSN: 0003-9861	19,20	TECHNICAL FIELDS SEARCHED (Int.CI.7)
Y	see the whole document	21-34, 50-56	
X	PAGE THEODORE ET AL: "Purification and characterization of human lymphoblast N-acetylglucosamine-1-phosphodiester alpha-N-acetylglucosaminidase." GLYCOBIOLOGY, vol. 6, no. 6, 1996, pages 619-626, XP009008337	19,20	
Y	ISSN: 0959-6658 see abstract and page 624, right column, last par.	21-34	
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O) EPO FORM 1503 09.98 (P04C26)



PARTIAL EUROPEAN SEARCH REPORT

Application Number

EP 00 96 1335

	DOCUMENTS CONSIDERED TO BE RELEVANT		CLASSIFICATION OF THE APPLICATION (Int.CI.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
Υ	BARANSKI THOMAS J ET AL: "Lysosomal enzyme phosphorylation: I. Protein recognition determinants in both lobes of procathepsin D mediate its interaction with UDP-GlcNAc:Lysosomal enzyme N-acetylglucosamine-1-phosphotransferase." JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 267, no. 32, 1992, pages 23342-23348, XP002235769 ISSN: 0021-9258 see the whole document	35-48	
Υ	TIKKANEN RITVA ET AL: "Several cooperating binding sites mediate the interaction of a lysosomal enzyme with phosphotransferase." EMBO (EUROPEAN MOLECULAR BIOLOGY ORGANIZATION) JOURNAL, vol. 16, no. 22, 17 November 1997 (1997-11-17), pages 6684-6693, XP002235770 ISSN: 0261-4189 see the whole document	35-48	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
X	MATSUURA ET AL: "Human alpha-galactosidase A: characterization of the N-linked oligosaccharides on the intracellular and secreted glycoforms overexpressed by Chinese hamster ovary cells" GLYCOBIOLOGY, IRL PRESS,, GB, vol. 8, no. 4, April 1998 (1998-04), pages 329-339, XP000925912 ISSN: 0959-6658 see abstract	49,57	

O) 503 09.98 (P04C26)

European Pat nt Office

PARTIAL EUROPEAN SEARCH REPORT

EP 00 96 1335

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
Х	MAGUCHI S ET AL: "ELEVATED ACTIVITY AND INCREASED MANNOSE 6-PHOSPHATE IN THE CARBOHYDRATE MOIETY OF CATHEPSIN D FROM HUMAN HEPATOMA" CANCER RESEARCH, vol. 48, no. 2, 1988, pages 362-367, XP009008325 ISSN: 0008-5472 see abstract	49,57	
х	BARTON N W ET AL: "THERAPEUTIC RESPONSE TO INTRAVENOUS INFUSIONS OF GLUCOCEREBROSIDASEIN A PATIENT WITH GAUCHER DISEASE" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE. WASHINGTON, US, vol. 87, March 1990 (1990-03), pages 1913-1916, XP002905934 ISSN: 0027-8424 see the whole document	74-81	TECHNICAL FIELDS SEARCHED (Int.CI.7)
X	BRADY R O ET AL: "Modifying Exogenous Glucocerebrosidase for Effective Replacement Therapy in Gaucher Disease." JOURNAL OF INHERITED METABOLIC DISEASE, vol. 17, no. 4, 1994, pages 510-519, XP009008428 ISSN: 0141-8955 see the whole document, esp. Fig. 4	74-81	

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PARTIAL EUROPEAN SEARCH REPORT

Application Number

EP 00 96 1335

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim		
Υ	KAKKIS E D ET AL: "OVEREXPRESSION OF THE HUMAN LYSOSOMAL ENZYME ALPHA-L-IDURONIDASE IN CHINESE HAMSTER OVARY CELLS" PROTEIN EXPRESSION AND PURIFICATION, ACADEMIC PRESS, US, vol. 5, no. 3, June 1994 (1994-06), pages 225-232, XP000857380 ISSN: 1046-5928 see the whole document	74-81		
Y	ZHAO KE-WEI ET AL: "Carbohydrate structures of recombinant human alpha-L-iduronidase secreted by Chinese hamster ovary cells." JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 272, no. 36, 1997, pages 22758-22765, XP002235771 ISSN: 0021-9258 see the whole document	74-81	TECHNICAL FIELDS SEARCHED (Int.CI.7)	
Y	ZIEGLER R J ET AL: "CORRECTION OF ENZYMATIC AND LYSOSOMAL STORAGE DEFECTS IN FABRY MICEBY ADENOVIRUS-MEDIATED GENE TRANSFER" HUMAN GENE THERAPY, XX, XX, vol. 10, no. 10, 1 July 1999 (1999-07-01), pages 1667-1682, XP001012918 ISSN: 1043-0342 see the whole document	74-81	·	
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SUPPLEMENTARY PARTIAL FUNCTION PARTIAL EUROPEAN SEARCH REPORT Application Number

EP 00 96 1335

	DOCUMENTS CONSIDERED TO BE RELEVANT		CLASSIFICATION OF THE APPLICATION (Int.CI.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
Υ	SUN HUAICHANG ET AL: "Retrovirus vector-mediated correction and cross-correction of lysosomal alpha-mannosidase deficiency in human and feline fibroblasts." HUMAN GENE THERAPY, vol. 10, no. 8, 20 May 1999 (1999-05-20), pages 1311-1319, XP009008322	74-81	
Y	ISSN: 1043-0342 see the whole document REUSER A J J ET AL: "Lysosomal storage diseases: Cellular pathology, clinical and genetic heterogeneity, therapy." ANNALES DE BIOLOGIE CLINIQUE, vol. 52, no. 10, 1994, pages 721-728, XP009008339 ISSN: 0003-3898 see pages 726-727 "Therapy"	74-81	TECHNICAL FIELDS SEARCHED (Int.CI.7)
	-		

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 00 96 1335

This annex lists the patent family members relating to the patent documents cited in the above–mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

26-03-2003

Patent docume cited in search re		Publication date		Patent fam member(s		Publication date
WO 9931117	A	24-06-1999	AU CA EP JP WO US AU CA EP JP WO US US US US US US US US US US US US US	2306499 2315295 1039801 1040117 2002508167 9854963 9931117 6525174 1931399 2314379 1044210 2002508166 9931116 2001024813 6552198 0973892	A A1 A1 A1 T A2 A1 B1 A A1 A1 T A1 A1 A1 A1 A1 A2 T A2	05-07-1999 24-06-1999 04-10-2000 19-03-2002 10-12-1998 24-06-1999 25-02-2003 05-07-1999 24-06-1999 18-10-2000 19-03-2002 24-06-1999 27-09-2001 29-09-1998 26-01-2000 04-12-2001 17-09-1998 10-09-2002
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